

CLAIMS

We claim:

1. Novel anhydrous amorphous forms of bis[(E) [4-(4-fluorophenyl) isopropyl [methyl(methylsulfonyl)amino]pyrimidin yl](3R,5S)-3,5-dihydroxyhept enoic acid]calcium salt (rosuvastatin calcium), bis[(E)-3,5-dihydroxy-7-[4'-(4''-fluorophenyl)-2'-cyclopropyl-quinolin-3'-hept-6-enoic acid] calcium salt (pitavastatin calcium) and (\pm)7-(3-(4-fluorophenyl)-1-(1-methylethyl)-1H-indol-2-yl)-3,5-dihydroxy heptenoic acid monosodium salt (fluvastatin sodium).
2. A novel anhydrous amorphous form of rosuvastatin calcium according to claim 1, characterized by an X-ray powder diffraction pattern substantially in accordance with Figure 1.
3. A novel anhydrous amorphous form of pitavastatin calcium according to claim 1, characterized by an X-ray powder diffraction pattern substantially in accordance with Figure 2.
4. A novel anhydrous amorphous form of fluvastatin sodium according to claim 1, characterized by an X-ray powder diffraction pattern substantially in accordance with Figure 3.
5. An anhydrous amorphous form as claimed in claim 1 which is a novel anhydrous amorphous form of rosuvastatin calcium.
6. An anhydrous amorphous form as claimed in claim 1 which is a novel anhydrous amorphous form of pitavastatin calcium.
7. An anhydrous amorphous form as claimed in claim 1 which is a novel anhydrous amorphous form of fluvastatin sodium.
8. A process for the preparation of anhydrous amorphous forms of bis[(E) [4-(4-fluorophenyl) isopropyl [methyl(methylsulfonyl)amino]pyrimidin yl](3R,5S)-3,5-dihydroxyhept enoic acid]calcium salts (rosuvastatin calcium), bis[(E)-3,5-dihydroxy-7-[4'-(4''-fluorophenyl)-2'-cyclopropyl-quinolin-3'-hept-6-enoic acid] calcium salt (pitavastatin calcium) and (\pm)7-(3-(4-fluorophenyl)-1-(1-methylethyl)-1H-indol-2-yl)-3,5-

dihydroxy heptenoic acid monosodium salt (fluvastatin sodium), which comprises the steps of:

- (a) dissolving crude or pure hydrate amorphous or crystalline form or their mixtures of the Agents in a non-hydroxylic solvent;
- (b) adding a non-polar hydrocarbon anti-solvent or adding the dissolved the Agents to the non-polar anti-solvent to precipitate out product;
- and (c) removing the solvent by filtration to afford anhydrous amorphous forms of rosuvastatin calcium, pitavastatin calcium and fluvastatin sodium.

9. The process according to claim 8 is for the preparation of anhydrous amorphous form of rosuvastatin calcium.

10. The process according to claim 8 is for the preparation of anhydrous amorphous form of pitavastatin calcium.

11. The process according to claim 8 is for the preparation of anhydrous amorphous form of fluvastatin sodium.

12. The process according to claim 8, wherein the Agents is chosen from rosuvastatin calcium, pitavastatin calcium or fluvastatin sodium.

13. The process according to claim 8, wherein the non-hydroxylic solvent is tetrahydrofuran and anti-solvent is chosen from a group of non-polar hydrocarbon solvents comprising n-hexane, cyclohexane or n-heptane.

14. The process according to claim 8, wherein the non-hydroxylic solvent is tetrahydrofuran and anti-solvent is n-hexane.

15. The process according to claim 8, wherein the non-hydroxylic solvent is tetrahydrofuran and anti-solvent is cyclohexane.

16. The process according to claim 8, wherein the non-hydroxylic solvent is tetrahydrofuran and anti-solvent is n-heptane.

17. The process according to any of claims 8-16, which comprises cooling the solution and isolating the precipitated anhydrous amorphous form by filtration or centrifuging.

18. A process for the preparation of anhydrous amorphous forms of rosuvastatin calcium, pitavastatin calcium and fluvastatin sodium by dissolving crude or pure hydrate amorphous or crystalline forms or their mixtures of the Agents in acetonitrile or in

straight or branched alkanol containing 1-4 carbon atoms or a mixture of such alkanols under heating and isolating the anhydrous amorphous form of the Agents precipitated after cooling.

19. The process according to claim 18 is for the preparation of anhydrous amorphous form of rosuvastatin calcium.

20. The process according to claim 18 is for the preparation of anhydrous amorphous form of pitavastatin calcium.

21. The process according to claim 18 is for the preparation of anhydrous amorphous form of fluvastatin sodium.

22. The process according to claim 18, wherein the Agents is chosen from rosuvastatin calcium, pitavastatin calcium or fluvastatin sodium.

23. The process according to claim 18, alkanol solvent is selected from methanol, ethanol, isopropanol, butanol or their mixtures.

24. The process according to claim 18, alkanol solvent is preferably selected from ethanol and isopropanol.

25. The process according to claim 18, which comprises using acetonitrile or a mixture of acetonitrile and one or more alkanols.

26. The process according to claim 18, which comprises dissolving rosuvastatin calcium or pitavastatin calcium or fluvastatin sodium in alkanols or acetonitrile at the boiling point of the solvent.

27. The process according to any of claims 18-26, which comprises cooling the solution and isolating the precipitated anhydrous amorphous form by filtration or centrifuging.

28. A pharmaceutical composition comprising an anhydrous amorphous form of rosuvastatin calcium, pitavastatin calcium or fluvastatin sodium and pharmaceutically acceptable carrier, diluent, excipient, additive, filler, lubricant, solvent binder or stabilizer.

29. A pharmaceutical composition as claimed in claim 28, which comprises an anhydrous amorphous form of rosuvastatin calcium.

30. A pharmaceutical composition as claimed in claim 28, which comprises an anhydrous amorphous form of pitavastatin calcium.

31. A pharmaceutical composition as claimed in claim 28, which comprises an anhydrous amorphous form of fluvastatin sodium.

32. A pharmaceutical composition according to claim 28, in the form of a tablet, troche, powder, syrup, patch, liposome, injection, dispersion, suspension, solutions, capsule, cream, ointment or aerosol.

33. The use of an effective amount of a compound according to any one of claims 1-7 for the manufacture of a medicament for treating, preventing or ameliorating hyperlipidemia, hypercholesterolemia and atherosclerosis.